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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,603	07/01/2003	Colombe Chappey	11068-065-999	4793
20583	7590	11/16/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,603

Applicant(s)

CHAPPEY ET AL.

Examiner

Louise Humphrey, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 12-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 12, 14, 15, 26, 27, 29, 32-34, 36, 37, 39, 40 and 42 is/are rejected.
- 7) ☒ Claim(s) 13, 16-25, 28, 30, 31, 35, 38 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Final Office Action is in response to the amendment filed on 17 August 2006. Claims 2-11 have been cancelled. Claims 1 and 12-42 are pending.

The objection to the disclosure **is withdrawn** in view of the Applicant's amendment.

The objection to claim 7 **is withdrawn** in view of the claim cancellation.

The rejection of claim 38 under 35 U.S.C. §112, second paragraph, as being indefinite **is withdrawn** in view of the amendment.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1, 2, 7, 8, 12, 14, 22, 26 and 42 under 35 U.S.C. §102(b) as being anticipated by Schmidt *et al.* (2000) **is withdrawn** in view of the amendment.

The rejection of claims 1, 7, 12, 19, 22, 26 and 42 under 35 U.S.C. §102(b) as being anticipated by Deeks *et al.* (1999) **is withdrawn** in view of the amendment.

The rejection of claims 1, 7, 12, 21, 22, 29, 32, 33, 36 and 39-42 under 35 U.S.C. §102(b) as being anticipated by Carrillo *et al.* (1998) **is withdrawn** in view of the amendment.

The rejections of claims 1, 7, 12, 23, 36, and 42 under 35 U.S.C. §102(b) as being anticipated by Croteau *et al.* (1996) **is withdrawn** in view of the amendment.

The rejection of claims 1, 7, 12, 15, 16, and 42 are rejected under 35 U.S.C. §102(b) as being anticipated by Jørgensen *et al.* (June 2001) **is withdrawn** in view of the amendment.

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The rejection of claims 1, 7, 12, 24, 36, and 42 under 35 U.S.C. §102(b) as being anticipated by Mascolini *et al.* (2000) **is withdrawn** in view of the amendment.

The rejection of claims 1, 2, 12, 22, 26, 36, and 42 under 35 U.S.C. §102(b) as being anticipated by Robinson *et al.* (2000) **is withdrawn in part for claims 2 and 22 due to claim cancellation and amendment, maintained in part for claims 1, 12, 26, 36 and 42, and extended to claim 15, 27, 29, 34, 37, 39, and 40.** Applicant's arguments, filed on 17 August 2006, have been fully considered and are not persuasive. Applicants assert that the Robinson reference does not teach each and every element of the invention as presently claimed. However, Applicants do not specifically point out the claim element that is not taught. Robinson *et al.* teach HIV-1 protease mutations detected in a clone isolated from a subject who had failed amprenavir (APV) therapy. The mutations that can be used to assess APV susceptibility include E34G, which reads on the claimed invention.

The rejection of claims 1, 7, 12, 19, 22, 29, 30, 36, and 42 under 35 U.S.C. §102(b) as being anticipated by Condra *et al.* (1996) **is withdrawn in part for claims 7 and 19 due to claim cancellation and amendment, maintained in part for claims 1, 12, 22, 29, 30, 36, and 42.** Applicants argue that Condra *et al.* do not teach every element of the claims. Examiner does not concur. Condra *et al.* teach APV resistant mutations L33I, Q58E, and V82F, as evidenced by the Stanford University HIV Drug Resistance Database (see attached printouts of query results), which are to be used in the assessment of APV susceptibility in an HIV-1 isolate. Therefore, Condra *et al.*

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clearly anticipate the instant invention.

The rejection of claims 1, 7, 12, 22, 26-28, 32-36, and 42 under 35 U.S.C. §102(b) as being anticipated by Palmer *et al.* (1999) **is withdrawn in part for claims 7 and 22 due to claim cancellation and amendment, maintained in part for claims 1, 12, 26-28, 32-36, and 42, and extended to claim 17.** Applicants argue that Palmer *et al.* do not teach every element of the claims. Examiner does not concur. Palmer *et al.* teach APV resistant mutations P79AS, I54T, and K43T, as evidenced by the Stanford University HIV Drug Resistance Database (see attached printouts of query results), which are to be used in the assessment of APV susceptibility in an HIV-1 isolate. Therefore, Palmer *et al.* clearly anticipate the instant invention.

The rejection of claims 1, 7, 12, 13, 16, and 42 under 35 U.S.C. §102(b) as being anticipated by Colonno *et al.* (2000) **is withdrawn in part for claims 7 and 16 due to claim cancellation and amendment, maintained in part for claims 1, 12, 13, and 42, and extended to claims 21.** Applicants argue that Colonno *et al.* do not teach every element of the claims. Examiner does not concur. Colonno *et al.* teach APV resistant mutations V11I, I54T, L76V, and K43T, as evidenced by the Stanford University HIV Drug Resistance Database (see attached printouts of query results), which are to be used in the assessment of APV susceptibility in an HIV-1 isolate. Therefore, Colonno *et al.* clearly anticipate the instant invention.

The rejection of claims 1, 7, 12, 14, 17, 20, 22, 26-28, 36, and 42 under 35 U.S.C. §102(a) as being anticipated by Kempf *et al.* (August 2001) **is withdrawn in part for claim 7, 22, and 26-28 due to claim cancellation and amendment,**

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maintained in part for claims 1, 12, 14, 17, 20, 36, and 42, and extended to claim

30. Applicants argue that Kempf *et al.* do not teach every element of the claims.

Examiner does not concur. Kempf *et al.* teach APV resistant mutations L33F, K43T, A71L, and Q58E, as evidenced by the Stanford University HIV Drug Resistance Database (see attached printouts of query results), which are to be used in the assessment of APV susceptibility in an HIV-1 isolate. Therefore, Kempf *et al.* clearly anticipate the instant invention.

The rejection of claims 1, 7, 12, 15, 16, and 42 under 35 U.S.C. §102(a) as being anticipated by Beerenwinkel *et al.* (June 2002) **is withdrawn in part for claims 7, 15, 16 and 22 due to claim cancellation and amendment, maintained in part for claims 1, 12, and 42, and extended to claims 14, 18, 19, 25, 29, 30, 32-37, 39, and 40.**

Applicants argue that Beerenwinkel *et al.* do not teach every element of the claims.

Examiner does not concur. Beerenwinkel *et al.* teach APV resistant mutations L33F, G48M, I54A, C95F, P79L, and T91I, as evidenced by the Stanford University HIV Drug Resistance Database (see attached printouts of query results), which are to be used in the assessment of APV susceptibility in an HIV-1 isolate. Therefore, Beerenwinkel *et al.* clearly anticipate the instant invention.

Specification

The amendment filed 17 August 2006 is objected to under 35 U.S.C. §132(a) because it introduces new matter into the disclosure. 35 U.S.C. §132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added

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material which is not supported by the original disclosure is as follows: a mutation associated with reduced susceptibility to treatment with said protease inhibitor is not I54V or V82A in claim 1 and the amino acid at position 79 is not P in claims 32 and 33.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, 32, and 33 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amended claim 1 includes a new negative limitation: "with the proviso that said mutation is not I54V, V82A," whereas the amended claims 32 and 33 includes a new negative limitation: "with the proviso that the amino acid at position 79 is not P," which are neither explicitly nor implicitly supported by the original disclosure or the specification. The specification positively recited the mutations, I54V, V82A, within the scope of invention. The specification does not recite that the amino acid at position 79 is not P. Therefore, the addition of exclusion of I54V, V82A and 79P to narrow down the original scope of invention is a new matter.

Claim Rejections - 35 USC § 102

Claims 1, 12, 14, 15, 26, 27, 29, 34, 36, 37, 39, 40, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Pausen *et al.* (2001).

The instant invention is indicated in the prior Office Action.

Pausen *et al.* teach the mutation L33F that is associated with APV resistance.

Thus, the instant invention is anticipated by Pausen *et al.*

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

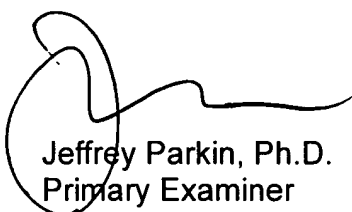
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.
Primary Examiner
8 November 2006

Lu H
11/8/2006